



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,432	07/29/2003	Christopher John Corcoran	031896-36000	5325

22204 7590 09/16/2005

NIXON PEABODY, LLP
401 9TH STREET, NW
SUITE 900
WASHINGTON, DC 20004-2128

EXAMINER

MOORE, WILLIAM W

ART UNIT	PAPER NUMBER
----------	--------------

1656

DATE MAILED: 09/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/628,432

Applicant(s)

CORCORAN ET AL.

Examiner

William W. Moore

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1656

DETAILED ACTION

Restriction

Restriction to one of the following inventions is required under 35 U.S.C. § 121:

- 1-18. Claims 1-9, each drawn in part to a modified ADAMTS4 having an amino acid sequence among those set forth in SEQ IDs NOs:17, 19, 22, 24, 26, 27, 29, 31, 32, 40 and 46-53, and to compositions comprising same, classified in class 435, subclass 212.
- 19-36. Claims 10-15, each drawn in part to a polynucleotide encoding a modified ADAMTS4 having an amino acid sequence among those set forth in SEQ IDs NOs:17, 19, 22, 24, 26, 27, 29, 31, 32, 40 and 46-53, to vectors comprising same, and to recombinant methods of making the encoded modified ADAMTS4 proteins utilizing host cells comprising the polynucleotides, classified, *inter alia*, in class 435, subclass 212.
- 37-54. Claim 16, drawn in part to methods of identifying an inhibitor of aggrecanase activity utilizing a modified ADAMTS4 having an amino acid sequence among those set forth in SEQ IDs NOs:17, 19, 22, 24, 26, 27, 29, 31, 32, 40 and 46-53, classified, in class 435, subclass 23.
- 55-72. Claims 17 and 18, each drawn in part to compositions comprising an unspecified inhibitor of the aggrecanase activity of a modified ADAMTS4 having an amino acid sequence among those set forth in SEQ IDs NOs:17, 19, 22, 24, 26, 27, 29, 31, 32, 40 and 46-53. Classification cannot be determined because the classification system is based on chemical structure and no structure of an inhibitor is disclosed in the specification.
- 73-90. Claims 17 and 18, each drawn in part to compositions comprising an antibody capable of recognizing a modified ADAMTS4 having an amino acid sequence among those set forth in SEQ IDs NOs:17, 19, 22, 24, 26, 27, 29, 31, 32, 40 and 46-53, classified in class 530, subclass 387.1.
- 91-108. Claims 19 and 20, each drawn in part to a method of treating a disease comprising the administration of an unspecified inhibitor of the aggrecanase activity of a modified ADAMTS4 having an amino acid sequence among those set forth in SEQ IDs NOs:17, 19, 22, 24, 26, 27, 29, 31, 32, 40 and 46-53. Classification cannot be determined because the classification system is based on chemical structure and no structure of an inhibitor is disclosed in the specification.
- 109-126. Claims 19 and 20, each drawn in part to a method of treating a disease comprising the administration of an antibody capable of recognizing a modified ADAMTS4 having an amino acid sequence among those set forth in SEQ IDs NOs:17, 19, 22, 24, 26, 27, 29, 31, 32, 40 and 46-53, classified in class 424, subclass 146.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups 1-18 are unrelated, one to another. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04,

Art Unit: 1656

MPEP § 808.01). In the instant case the different inventions are 18 structurally distinct proteases, each requiring a separate search in the patent and non-patent literature, and none are disclosed as capable of use together and each has different effects.

Because these inventions are distinct for the reasons given above and the search required for any one of Groups 1-18 is not required for another of Groups 1-18, restriction for examination purposes as indicated is proper.

Inventions of Groups 19-36 are unrelated, one to another. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are polynucleotides encoding 18 structurally distinct proteases, each polynucleotide requiring a separate search in the patent and non-patent literature, and none are disclosed as capable of use together and each has different effects.

Because these inventions are distinct for the reasons given above and the search required for any one of Groups 19-36 is not required for another of Groups 19-36, restriction for examination purposes as indicated is proper.

Inventions of Groups 37-54 are unrelated, one to another. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are methods requiring one of 18 structurally distinct proteases, each requiring a separate search in the patent and non-patent literature, wherein the different methods that are not disclosed as capable of use together and have different effects.

Because these inventions are distinct for the reasons given above and the search required for any one of Groups 37-54 is not required for another of Groups 37-54, restriction for examination purposes as indicated is proper.

Inventions of Groups 55-72 are unrelated, one to another. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions require compositions comprising inhibitors of one of 18 structurally distinct proteases, each requiring a separate search in the patent and non-patent literature, wherein the different compositions are not disclosed as capable of use together and have different effects.

Art Unit: 1656

Because these inventions are distinct for the reasons given above and the search required for any one of Groups 55-72 is not required for another of Groups 55-72, restriction for examination purposes as indicated is proper.

Inventions of Groups 73-90 are unrelated, one to another. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions require antibodies capable of binding to one of 18 structurally distinct proteases, each requiring a separate search in the patent and non-patent literature, wherein the different antibodies are not disclosed as capable of use together and have different effects.

Because these inventions are distinct for the reasons given above and the search required for any one of Groups 73-90 is not required for another of Groups 73-90, restriction for examination purposes as indicated is proper.

Inventions of Groups 91-108 are unrelated, one to another. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are methods requiring the administration of inhibitors of one of 18 structurally distinct proteases, each requiring a separate search in the patent and non-patent literature, wherein the different methods are not disclosed as capable of use together and have different effects.

Because these inventions are distinct for the reasons given above and the search required for any one of Groups 91-108 is not required for another of Groups 91-108, restriction for examination purposes as indicated is proper.

Inventions of Groups 109-126 are unrelated, one to another. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are methods requiring the administration of antibodies capable of binding of one of 18 structurally distinct proteases, each requiring a separate search in the patent and non-patent literature, wherein the different methods are not disclosed as capable of use together and have different effects.

Because these inventions are distinct for the reasons given above and the search required for any one of Groups 109-126 is not required for another of Groups 109-126, restriction for examination purposes as indicated is proper.

Art Unit: 1656

Inventions of Groups 1-18 and Groups 19-36 are related, respectively, as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the products as claimed can be made by another and materially different process, such as solid phase chemical synthesis.

Inventions of Groups 1-18 and Groups 37-54 are related, respectively, as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products as claimed can be used in materially different processes of using the products, such as *in vitro* methods of proteolytic processing of aggrecan.

Inventions of Groups 1-18 and Groups 55-72 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed to have any structural or functional relationship, thus require separate searches in the patent and non-patent literature, and are not disclosed to be capable of use together, and have different modes of operation, different functions, and different effects.

Inventions of Groups 1-18 and Groups 73-90 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have no structural or functional relationship, thus require separate searches in the patent and non-patent literature, and are not disclosed to be capable of use together and have different modes of operation, different functions, and different effects.

Inventions of Groups 1-18 and Groups 91-108 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed

Art Unit: 1656

to be capable of use together and have different modes of operation, different functions, and different effects.

Inventions of Groups 1-18 and Groups 109-126 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed to be capable of use together and have different modes of operation, different functions, and different effects.

Inventions of Groups 19-36 and Groups 37-54 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed to be capable of use together and have different modes of operation, different functions, and different effects.

Inventions of Groups 19-36 are unrelated to the inventions of Groups 55-72 and Groups 73-90. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups 19-36 cannot be comprised by compositions of the inventions of Groups 55-90 and the different inventions are not disclosed to be capable of use together, and have different modes of operation, different functions, and different effects.

Inventions of Groups 19-36 are unrelated to the inventions of Groups 91-108 and Groups 109-126. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups 19-36 cannot be comprised by compositions used in methods of inventions of Groups 91-126 and the different inventions are not disclosed to be capable of use together, and have different modes of operation, different functions, and different effects.

Inventions of Groups 37-54 and Groups 55-72 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and

Art Unit: 1656

they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed to be capable of use together and have different modes of operation, different functions, and different effects.

Inventions of Groups 37-54 and Groups 73-90 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed to be capable of use together and have different modes of operation, different functions, and different effects.

Inventions of Groups 37-54 and Groups 91-108 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed to be capable of use together and have different modes of operation, different functions, and different effects.

Inventions of Groups 37-54 and Groups 109-126 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed to be capable of use together and have different modes of operation, different functions, and different effects.

Inventions of Groups 55-72 and Groups 73-90 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case components of the different compositions of Groups 55-72 are not disclosed to have any structural or functional relationship to the components of compositions of Groups 73-90, thus require separate searches in the patent and non-patent literature, and are not disclosed to be capable of use together and have different modes of operation and different effects.

Inventions of Groups 55-72 and Groups 91-108 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can

Art Unit: 1656

be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the processes for using the products as claimed can be practiced with another materially different product, such as the antibodies of Groups 109-126.

Inventions of Groups 55-72 and Groups 109-126 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed to be capable of use together and have different modes of operation, different functions, and different effects.

Inventions of Groups 73-90 and Groups 91-108 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed to be capable of use together and have different modes of operation and different effects.

Inventions of Groups 73-90 and Groups 109-126 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the processes for using the products as claimed can be practiced with other, materially different, products, such as the aggrecanase inhibitors of Groups 91-108.

Inventions of Groups 91-108 and Groups 109-126 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed to be capable of use together and have different modes of operation and different effects.

Art Unit: 1656

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Election

A telephone call was made Mr. Raymond Van Dyke on 13 September 2005 to request an oral election to the above restriction requirement, but did not result in an election being made. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Notice of Requirements for Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier.** Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. §§101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised

Art Unit: 1656

that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**


Further, note that the prohibition against double patenting rejections of 35 U.S.C. § 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 571.272.0933 and whose FAX number is 571.273.0933. The examiner can normally be reached Monday through Friday between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisory Primary Examiner, Dr. Kathleen Kerr, can be reached at 571.272.0931. The official FAX number for all communications for the organization where this application or proceeding is assigned is 571.273.8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571.272.1600.

William W. Moore
13 September 2005


NASHAAT T. NASHED PHD.
PRIMARY EXAMINER